UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UMB BANK, N.A., solely in its capacity as Trustee under the Contingent Value Rights Agreement by and between Bristol-Myers Squibb Company and Equiniti Trust Company, dated November 20, 2019, Plaintiff, v. BRISTOL-MYERS SQUIBB COMPANY, Defendant.	Case No. 1:21 Civ. 4897 (JMF) ORAL ARGUMENT REQUESTED

OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

Date: September 14, 2021

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Plaintiff UMB Bank, N.A. ("Trustee" or "UMB"), solely in its capacity as Trustee under the Contingent Value Rights Agreement ("CVR Agreement") by and between Bristol-Myers Squibb Company ("Bristol-Myers") and Equiniti Trust Company ("Equiniti"), dated November 20, 2019, submits this memorandum of law in opposition to Bristol-Myers's memorandum of law ("Br.") (Dkt. 18) filed in support of its motion to dismiss ("Motion") (Dkt. 17), which seeks to dismiss the Trustee's Complaint, filed on June 3, 2021 ("Complaint" or "Compl.") (Dkt. 1).

PRELIMINARY STATEMENT

Bristol-Myers repeatedly breached the Diligent Efforts provision of its CVR Agreement by improperly delaying Food and Drug Administration ("FDA") approval of lisocabtagene maraleucel ("Liso-cel"), a life-saving treatment for non-Hodgkins lymphoma. These breaches caused the Liso-cel approval milestone to be missed, and as a result, the holders of contingent value rights ("CVRs") lost approximately $6.4 billion. To try to avoid liability and billions in damages for its wrongful acts—allegations of which must be assumed to be true for purposes of this Motion—Bristol-Myers reads the CVR Agreement's notice and termination provisions irrationally. It contends that the Trustee cannot sue unless a breach "continues" for ninety days after notice of the breach—and that any breach ceases to "continue" once the CVR Agreement terminates. It is undisputed that the Trustee provided Bristol-Myers notice on March 4, 2021 and waited ninety days before suit. But, according to Bristol-Myers, the Trustee cannot hold Bristol-Myers accountable for its breaches because the CVR Agreement terminated before the ninety days lapsed.

No reasonable party to the CVR Agreement would agree to give Bristol-Myers a license to breach the CVR Agreement with impunity during the last ninety days of its term. And no party has. Bristol-Myers's construction is contradicted by the CVR Agreement's plain language and precedent, including a 2020 decision by this Court that rejected an almost identical argument. *See N.Y. Wheel Owner LLC v. Mammoet Holding B.V.*, 481 F. Supp. 3d 216, 237 (S.D.N.Y. 2020)

(Furman, J.). Its Motion fails for three independently dispositive reasons: (1) the Trustee noticed a continuing default, pursuant to a provision that expressly survives termination, and waited ninety days before suit; (2) black-letter law precludes Bristol-Myers from causing termination by breaching the CVR Agreement and then relying on that termination to absolve itself from liability for the breaches; and (3) an Event of Default is not necessary for the Trustee to bring suit.

The CVR Agreement was executed as part of Bristol-Myers's acquisition of Celgene Corporation ("Celgene"), the developer of Liso-cel. The CVR Agreement obligated Bristol-Myers to pay $9 to each CVR holder, approximately $6.4 billion in total, if Liso-cel and two other Celgene therapies received FDA approval by contractually set dates (the "Milestones"). The CVR Agreement required Bristol-Myers to use Diligent Efforts to achieve FDA approval by these Milestones—meaning that Bristol-Myers had to work diligently towards obtaining approval and not sit idly by or sabotage the approval process. As CVR holders are outsiders to Bristol-Myers's efforts, the CVR Agreement gave the Trustee contractual rights to inspect Bristol-Myers's books and records and to enforce the CVR Agreement if Bristol-Myers breached.

Once Bristol-Myers took control of Liso-cel, its mismanagement of the FDA approval process resulted in one inexcusable delay after another. In a highly atypical move, Bristol-Myers decided to omit critical data from the Liso-cel Biologics License Application ("BLA"), which is the application submitted for FDA review and approval. The FDA predictably requested the omitted information. When Bristol-Myers amended its application to provide it, Bristol-Myers triggered an automatic three-month delay of the FDA's target date for a decision. Then when the FDA noticed and conducted inspections in October and December 2020 at what Bristol-Myers previously described as "launch-ready" facilities for the production of Liso-cel, Bristol-Myers did not adequately prepare. The FDA found that the facilities failed to meet numerous basic FDA and

industry standards—including failing to maintain procedures to prevent contamination of sterile drug products, failing to segregate materials rejected by quality control, retaining expired material, and leaving overturned bottles strewn at the bottom of freezers—further delaying Liso-cel's approval. Bristol-Myers's written responses to the FDA's findings at the inspection sites contained "unclear and questionable points" and drew further questions from the FDA, creating even more delay. These multiple deficiencies in basic protocols also breached Bristol-Myers's Diligent Efforts obligation and caused Bristol-Myers to miss the Liso-cel Milestone by just thirty-six days. Had Bristol-Myers used Diligent Efforts and not caused months of delay, the December 31, 2020 Liso-cel Milestone would have been met.

Bristol-Myers has stonewalled the Trustee's attempts to investigate Bristol-Myers's conduct. When the Trustee sought to exercise its contractual right to examine Bristol-Myers's books and records to assess compliance with the Diligent Efforts obligation, Bristol-Myers refused to comply. When the Trustee gave notice of Bristol-Myers's breaches of its Diligent Efforts and books and records obligations, Bristol-Myers refused to remedy them.

Bristol-Myers's Motion relies on a plainly incorrect interpretation of the CVR Agreement to seek dismissal of the Trustee's claims. Bristol-Myers argues that the CVR Agreement's termination upon the failure to meet the Liso-cel Milestone—the direct result of its breaches of the Diligent Efforts obligation—simultaneously terminated the Trustee's ability to bring suit to hold Bristol-Myers accountable. Bristol-Myers reasons that when the CVR Agreement terminated upon its failure to meet the Milestone, its breaches ceased to "continue"—even though Bristol-Myers has never remedied the breaches. From this false premise, Bristol-Myers draws the flawed conclusion that the breaches could not continue for ninety days after the Trustee provided notice on March 4, 2021, and thus the breaches supposedly never became Events of Default.

Bristol-Myers's attempt to evade its obligations fails for numerous reasons. First, the CVR Agreement expressly states that its termination "shall not relieve any Party of any liability arising from any material breach of its obligations under this CVR Agreement occurring prior to the Termination Date." Compl. Ex. A (CVR Agreement) § 1.16. It also states that the Trustee's enforcement powers—along with the provisions defining an Event of Default—"survive termination." *Id.* Any pre-termination breach becomes an Event of Default if it continues for ninety days after it is noticed, irrespective of the termination date. *Id.* § 8.1(b). The Trustee noticed breaches, Bristol-Myers provided no remedy, and the breaches have continued unremedied for more than ninety days.

Caselaw confirms this straightforward reading of the CVR Agreement. In *New York Wheel*, this Court rejected the same argument Bristol-Myers advances: that a "default was not 'continuing' because the agreement was terminated." 481 F. Supp. 3d at 236. This Court explained that a default continues until it is remedied, regardless of termination, because "termination of an agreement does not change th[e] state of affairs; the terminated party remains liable for the breach." *Id.* at 237. This Court further explained that the requirement for a "continuing" default is that the default be unremedied—and that the default is not extinguished upon termination. *Id.* So too here.

Were there any doubt, the absurd result of Bristol-Myers's misinterpretation eliminates it. Its reading would immunize any breaches occurring within ninety days of the CVR Agreement's termination. That means Bristol-Myers could, within ninety days of termination, abandon its obligations, take no action, or even withdraw the BLA without liability. This exception is not just hypothetical: many of the alleged breaches—including those related to the critical facility inspections—occurred within ninety days of the CVR Agreement's termination. Under Bristol-Myers's

reading, these breaches could never become Events of Default, and the Trustee could never enforce them. Effectively, the Trustee would lose the ability to enforce the CVR Agreement ninety days before it terminated.

Second, it is black-letter law that a party may not insist upon a condition precedent when the condition is not satisfied because of that party's misconduct. Yet that is precisely what Bristol-Myers is doing. It asserts that the CVR Agreement's termination precludes an Event of Default, but Bristol-Myers wrongfully caused that termination by breaching its Diligent Efforts obligation and missing the Liso-cel Milestone.

Third, an Event of Default is not needed for the Trustee to bring suit. The CVR Agreement obligates the Trustee to bring suit upon an Event of Default. Compl. Ex. A § 8.1 (providing that if there is an Event of Default, the Trustee "shall bring suit"). But the CVR Agreement provides that the Trustee may bring suit in its discretion regardless of an Event of Default, stating that "[n]othing in this CVR Agreement shall impair the right of the Trustee in its discretion to take any action deemed proper by the Trustee." *Id.* § 8.9(b). This power survives the termination of the CVR Agreement. *See id.* § 1.16.

Finally, Bristol-Myers cannot avoid the consequences of breaching its obligation to provide the Trustee with access to Bristol-Myers's books and records. Bristol-Myers doubles down on its defective Event of Default argument, asserting that its breach did not continue for ninety days after notice because the CVR Agreement terminated. In so doing, it again highlights the absurdity of its position. Bristol-Myers breached its obligation to provide its books and records days before the CVR Agreement terminated, so if Bristol-Myers were correct, the Trustee could never seek a judicial remedy for this breach. Bristol-Myers's secondary argument that it did not have enough time to comply with the Trustee's request before the CVR Agreement terminated, at best, raises

fact issues not suited for a motion to dismiss. Bristol-Myers's contention that the Trustee has failed to plausibly allege its damages were caused by Bristol-Myers's breach is also unavailing on a motion to dismiss, where all well-pleaded facts are assumed to be true. Bristol-Myers's Motion should be denied.

BACKGROUND

A. Bristol-Myers Issues $6.4 Billion Of Contingent Value Rights As Part Of Its Acquisition Of Celgene

In September 2018, international pharmaceutical giant Bristol-Myers proposed a merger with Celgene, an innovative biotech company with a strong pipeline of therapies in development, that would result in Celgene becoming Bristol-Myers's wholly owned subsidiary. Compl. ¶ 28. Celgene and Bristol-Myers negotiated the terms of the merger for approximately six months, with Celgene's valuation the main point of contention. *Id.* To bridge this valuation gap, Bristol-Myers offered to issue Celgene shareholders CVRs as additional consideration for the merger. *Id.* ¶ 29.

A CVR is a security that generally requires the issuer to make a payment to the holder if contractually specified events occur by contractually specified dates. *Id.* After intense negotiations over the terms of the CVR Agreement, Bristol-Myers and Celgene ultimately agreed that each CVR would carry a one-time payment of $9 for its holder, amounting to approximately $6.4 billion, if the FDA approved the marketing applications—known as BLAs for biologics and New Drug Applications for drugs—for three therapies (collectively, the "Milestone Therapies"). *Id.* ¶¶ 31–32. Specifically, the FDA would have to approve (1) Liso-cel, which treats diffuse large B-cell non-Hodgkin's lymphoma, by December 31, 2020; (2) Ozanimod, which treats relapsing multiple sclerosis, by December 31, 2020; and (3) Ide-cel, which treats relapsed and refractory multiple myeloma, by March 31, 2021. *Id.* If these three therapies were approved by their respective Milestones, then Bristol-Myers would owe the CVR holders a total of about $6.4 billion. *Id.*

¶ 32. If any deadline were missed, then Bristol-Myers would owe nothing. *Id.* Bristol-Myers and UMB's predecessor, Equiniti, which was acting on behalf of Celgene shareholders, executed the CVR Agreement on November 20, 2019. Compl. Ex. A at 1. The CVR Agreement empowered the Trustee to enforce the rights of CVR holders, including, if necessary, by bringing litigation against Bristol-Myers. *See id.* Art. 8.

The CVR Agreement's binary structure, standing alone, would have created a perverse economic incentive. Once the merger closed, Bristol-Myers controlled the development of the Milestone Therapies and could eliminate its approximately $6.4 billion CVR liability, while retaining substantially all the upside, by delaying FDA approval for just one of the three Milestone Therapies. Compl. ¶ 33. To protect against this, the CVR Agreement requires Bristol-Myers to "use Diligent Efforts to achieve the Milestone[s]." Compl. Ex. A § 7.8. The CVR Agreement defines "Diligent Efforts" to mean, in relevant part, the "efforts of a Person to carry out its obligations in a diligent manner using such effort and employing such resources normally used by such Person in the exercise of its reasonable business discretion relating to the research, development or commercialization of a product, that is of similar market potential at a similar stage in its development or product life." *Id.* § 1.1. This requirement mandated that Bristol-Myers affirmatively work to achieve approval of the Milestone Therapies by their respective deadlines and barred it from remaining idle or intentionally taking steps to delay FDA approval. Compl. ¶ 34.

The CVR Agreement recognizes that CVR holders, as outsiders, would have substantial barriers to assessing Bristol-Myers's internal compliance with its Diligent Efforts obligation. So, the CVR Agreement includes three provisions to ensure accountability and guard against Bristol-Myers evading its obligations by concealing relevant information. First, the CVR Agreement requires Bristol-Myers and its subsidiaries to "use commercially reasonable efforts to keep … true,

complete and accurate records in reasonably sufficient detail to enable the [CVR] Holders to determine if [Bristol-Myers] has complied with its obligations under this CVR Agreement" and to maintain those records for at least three years after the termination of the CVR Agreement. Compl. Ex. A § 7.5. Second, the CVR Agreement authorizes the Trustee to obtain those books and records, providing that the Trustee "shall be entitled to examine the pertinent books and records of [Bristol-Myers]" to investigate "the facts or matters stated in any … statement, instrument, opinion, report, notice … or other paper or document." *Id.* § 4.2(f). And third, the CVR Agreement places an affirmative obligation on Bristol-Myers to provide "the Trustee written notice of the occurrence of any Event of Default or other default under this CVR Agreement within five (5) Business Days of its becoming aware of such Event of Default or other default." *Id.* § 7.11.

The CVR Agreement also provides that after a missed Milestone deadline, the CVR Agreement terminates, but it expressly states that key provisions survive, including Article 8, which contains the notice provision at issue. *Id.* § 1.16. Additionally, it states that "the termination of this CVR agreement shall not relieve any Party of any liability arising from any material breach of its obligations under this CVR Agreement occurring prior to the Termination Date." *Id.*

B. Liso-Cel Was On The Fast Track For FDA Approval

For years, Liso-cel was on the fast track for FDA approval. Liso-cel, also known as JCAR017 and by its trade name Breyanzi, is a lifesaving therapy for highly vulnerable patients with advanced-stage cancer. Compl. ¶ 39. It is a chimeric antigen receptor T-cell therapy ("CAR-T Therapy") that treats patients with diffuse large B-cell non-Hodgkin's lymphoma, which is the most common non-Hodgkin's lymphoma. *Id.* Liso-cel treats extremely ill patients for whom prior treatments have failed. *Id.* Like other CAR-T Therapies, Liso-cel treats this terminal disease by extracting a cancer patient's T-cells, which are white blood cells that kill infected or cancerous cells, genetically modifying them to target and kill B-cells that have become malignant, and then

injecting the genetically modified T-cells into the patient, where they attack and kill malignant B-cells. *Id.* In clinical trials, Liso-cel proved to be more effective and to have fewer side effects than other similar treatments. *Id.* ¶¶ 40, 43. Given Liso-cel's promise, the FDA expedited its development and review process by designating Liso-cel a Breakthrough Therapy in 2016 and a Regenerative Medicine Advanced Therapy in 2017. *Id.* ¶ 41. Those designations ensured intensive, interactive FDA guidance during the therapy's development, with senior FDA personnel involved in a proactive, collaborative review of the therapy. *Id.* Before Bristol-Myers took the reins, all signs pointed to an expeditious FDA review process.

C. After Bristol-Myers Takes Control, The Milestone Therapies Suffer Numerous Setbacks

Celgene submitted the first component of the Liso-cel BLA on September 30, 2019. *Id.* ¶ 46. But Bristol-Myers took control before the filing of a critical section of the BLA—the Chemistry, Manufacturing, and Controls ("CMC") section, which specifies the manufacturing processes, product characteristics, and product testing upon which the manufacturer relies to ensure that its therapy is safe, effective, and consistently manufactured. *Id.* The FDA then conducted an initial review to determine whether the BLA was complete and whether to grant Priority Review, a designation reserved for therapies that are significant improvements to the safety or efficacy of the treatment, diagnosis, or prevention of a serious condition. *Id.* ¶ 47. When the FDA grants Priority Review, the Prescription Drug User Fee Act ("PDUFA") date—the target date for an FDA decision on approval, which the FDA endeavors to meet at least 90% of the time—reduces from ten months following the completion of the initial review to just six months. *Id.* ¶¶ 48–49.

The FDA completed its initial review and granted Liso-cel Priority Review on February 13, 2020, setting August 17, 2020 as the PDUFA date for Liso-cel. *Id.* ¶ 50. That date was well within the December 31, 2020 Milestone for Liso-cel. But Bristol-Myers squandered the benefits

of Priority Review. When it filed the Liso-cel BLA's CMC section on December 18, 2019, Bristol-Myers made a highly irregular decision to omit basic data detailing (1) the tests used to ensure that Liso-cel is safe and efficacious, referred to as assays, and (2) the studies of whether those assays worked as they were supposed to, referred to as validation. *Id.* ¶ 52. Unsurprisingly, the FDA submitted an information request to Bristol-Myers on March 23, 2020 to obtain this necessary data. *Id.* ¶ 53. Bristol-Myers amended its BLA nearly a month later on April 15, 2020 to provide this missing data. *Id.* As Bristol-Myers should have known, the amendment to add the missing data was so substantial that the FDA deemed it a "major amendment." *Id.* Major amendments are rare in general, and even rarer for a therapy like Liso-cel that has received the intensive FDA guidance accompanying Breakthrough Therapy and Regenerative Medicine Advanced Therapy designations. *Id.* ¶ 55. Major amendments are also highly problematic because they automatically trigger a three-month extension to the PDUFA date. *Id.* ¶ 53. Here, the major amendment caused the PDUFA date to move from August 17, 2020 to November 16, 2020, just weeks before the December 31, 2020 Liso-cel Milestone. *Id.*

Bristol-Myers's wrongful delays extended beyond Liso-cel. Just one week after the FDA declared the major amendment for Liso-cel, the FDA issued a refuse-to-file decision for the only other Milestone Therapy still awaiting FDA approval—Ide-cel.[1] *Id.* ¶ 58. Ide-cel, like Liso-cel, had received Breakthrough Therapy designation, ensuring that the FDA would be deeply involved in the development and review process. *Id.* ¶ 57. But on March 31, 2020, Bristol-Myers submitted a BLA for Ide-cel that was so materially deficient that the FDA refused to review it. *Id.* ¶ 58. A refuse-to-file decision occurs only when there is a clear failure, such as omissions of critical data

[1] The New Drug Application for the third therapy, Ozanimod, was submitted well before the merger, and the FDA approved it on March 26, 2020. Compl. ¶ 51.

on safety, purity, and potency, or if there is inadequate content, presentation, or organization of information such that meaningful review is precluded. *Id.*

Only 98 out of 2,475 BLAs and New Drug Applications submitted between 2008 and 2017 received a refuse-to-file decision. *Id.* Such decisions usually signify an applicant's unfamiliarity with the basics of the FDA application process. *Id.* A refuse-to-file decision is extremely rare for a major pharmaceutical company like Bristol-Myers, and rarer still for a therapy that has received Breakthrough Therapy designation. *Id.* After receiving the refuse-to-file decision, Bristol-Myers continued to stall, waiting over two months to file an adequate BLA, which pushed the start of the FDA's formal review to September 22, 2020—approximately four months after the formal review would have otherwise commenced. *Id.* ¶¶ 59–60.

After these fundamental failures, Bristol-Myers should have ensured that no more unwarranted delays occurred in order to meet the Milestones. But it did not do so. Instead, it botched another crucial step in the FDA review process: the pre-license inspections of the Liso-cel manufacturing facilities. *Id.* ¶ 61. The pre-license inspection aims to ensure that the facilities used to manufacture a therapy comply with basic FDA safety regulations and requirements. *Id.* The two facilities that were to be inspected for Liso-cel were the Lonza Group AG facility (the "Lonza Facility") in Houston, Texas and the Bristol-Myers facility in Bothell, Washington (the "Juno Facility"). *Id.* ¶ 63. Bristol-Myers develops the viral vector (the component of Liso-cel that identifies malignant B-cells) at the Lonza Facility and completes the production of Liso-cel at the Juno Facility. *Id.* Bristol-Myers must ensure that both facilities comply with FDA regulations, including by monitoring and instructing its contract vendor Lonza concerning FDA compliance. *Id.*

Bristol-Myers had publicly described the Liso-cel facilities as "launch ready" shortly after acquiring Celgene. *Id.* ¶ 64. But despite notice from the FDA and ample time to prepare both

facilities for inspection, the facilities fell short of basic safety and regulatory requirements when the FDA arrived. *Id.* The FDA inspected the Juno Facility from October 7, 2020 to October 16, 2020. *Id.* ¶ 65. After the inspection, the FDA issued a Form 483, which documents significant issues that may violate FDA regulations because they pose a risk that the therapy could be adulterated and harm patients. *Id.* Nearly a month after the inspection, Bristol-Myers responded to the FDA, admitting many of its failures and stating that it would take actions to enhance its processes and controls further and improve the overall effectiveness of its operations and quality systems. *Id.* ¶ 67. But Bristol-Myers's response was deficient, resulting in the FDA pointing to "unclear and questionable points" in the response, which Bristol-Myers was required to supplement. *Id.* Bristol-Myers did not complete its response until December 18, 2020, over a month after the PDUFA date and a matter of days before the Liso-cel Milestone. *Id.*

These issues at the Juno Facility and the delay they caused should have galvanized Bristol-Myers to ensure that the Lonza Facility fully complied with FDA guidance. Instead, the FDA's inspection of the Lonza Facility from December 3, 2020 to December 10, 2020 revealed a "litany of errors," including mistakes as basic and troubling as intermingling materials that were considered acceptable for use with ones that had been rejected by quality control, failing to dispose of expired material, and leaving overturned bottles strewn at the bottom of freezers. *Id.* ¶¶ 69, 71. Many of the errors identified overlapped with issues identified at the Juno Facility. *Id.* ¶ 69. Bristol-Myers's response to the Form 483 documenting these errors was yet again deficient and required further supplementation. *Id.* ¶ 72. All told, Bristol-Myers did not complete its response until December 23, 2020, mere days before the Liso-cel Milestone. *Id.*

D. The Trustee Requests Bristol-Myers's Books And Records

On December 29, 2020, the Trustee sent a letter to Bristol-Myers requesting that Bristol-Myers provide certain books and records to allow the Trustee to assess whether Bristol-Myers had

complied with its Diligent Efforts obligation. *See id.* ¶¶ 74–75. Bristol-Myers refused. *Id.* ¶ 77. To date, in defiance of its obligations, it has provided the Trustee no information, leaving the Trustee to sift through public records—many of which were not made available until after the Liso-cel Milestone—to assess Bristol-Myers's compliance with its Diligent Efforts obligation. *Id.*

E. The FDA Approves Liso-cel Thirty-Six Days After The Liso-cel Milestone

After the major amendment (which caused a three-month delay), two calamitous facility inspections resulting in Forms 483, and inadequate responses to those Forms 483, the December 31, 2020 Liso-cel Milestone lapsed without FDA approval. *Id.* ¶ 78. Bristol-Myers wasted no time in notifying its shareholders and the public that it no longer had a $6.4 billion liability, issuing a press release on January 1, 2021, stating that the CVR Agreement had terminated and that the CVRs would no longer trade on the New York Stock Exchange. *Id.* ¶ 79.

Just thirty-six days later, the FDA approved the Liso-cel BLA. *Id.* ¶ 80. Although Liso-cel barely missed the Milestone—by many fewer days than the delay Bristol-Myers's missteps had caused—the 415 days from submission of the Liso-cel BLA to approval was substantially longer than the time for other CAR-T Therapies. *Id.* ¶ 84. Those other CAR-T Therapies averaged just 194 days from submission to approval, and none ever received a major amendment. *Id.* ¶¶ 83–84.

F. The Trustee Files Suit Ninety Days After Noticing Breaches

On March 4, 2021, the Trustee notified Bristol-Myers that Bristol-Myers had breached its obligations to use Diligent Efforts to achieve the Liso-cel Milestone and to allow the Trustee to investigate Bristol-Myers's books and records. *Id.* ¶ 86. For ninety days, those breaches continued without Bristol-Myers offering any remedy. *Id.* To date, Bristol-Myers has not offered any remedy. On June 3, 2021, ninety-one days after the notice, the Trustee filed this suit to protect the CVR holders from Bristol-Myers's breaches of its obligations.

ARGUMENT

I. Bristol-Myers's Attempt To Evade Liability For Its Breaches Fails

Bristol-Myers attempts to use the CVR Agreement's notice provision to evade its approximately $6.4 billion liability, arguing that once the CVR Agreement terminated, Bristol-Myers's breaches of its Diligent Efforts obligation ceased to "continue" and could not become Events of Default. That argument is foreclosed by (1) the unambiguous terms of the CVR Agreement, (2) caselaw, including a recent decision from this Court that rejected the argument Bristol-Myers makes here, and (3) commercial reasonableness. *See infra* I.A. Even if that were not the case, it is black-letter law that Bristol-Myers cannot cause the failure of a condition precedent—here, the purported failure of an Event of Default—and then rely on that failed condition to avoid liability. *See infra* I.B. And, regardless, an Event of Default is not even a requirement for this suit. Section 8.9(b) of the CVR Agreement expressly provides that "[n]othing in this CVR Agreement shall impair the right of the Trustee in its discretion to take any action deemed proper by the Trustee," which includes the Trustee's decision to bring suit. *See infra* I.C. The Motion should be denied.

A. An Event Of Default Has Occurred And Is Continuing

Termination of the CVR Agreement does not preclude suit for a pre-termination breach. The CVR Agreement expressly provides that the ability to bring suit to address an Event of Default survives termination: "Article 8 … shall survive termination of this CVR Agreement." Compl. Ex. A § 1.16. Section 8.1, which is part of Article 8, states that "[i]f an Event of Default … occurs and is continuing, then … the Trustee … shall bring suit to protect the rights of the Holders." Section 8.1(b), which is also part of Article 8, specifies that an Event of Default occurs if there is a "material default in the performance, or breach in any material respect, of any covenant" and that default or breach continues "for a period of ninety (90) days after there has been given … a written notice specifying such default or breach and requiring it to be remedied." To avoid any doubt, the

CVR Agreement further provides that "the termination of this CVR Agreement shall not relieve any Party of any liability arising from any material breach of its obligations under this CVR Agreement occurring prior to the Termination Date." *Id.* § 1.16.

The Trustee has more than plausibly alleged an Event of Default under Section 8.1(b). Specifically, the Trustee has alleged that Bristol-Myers breached the Diligent Efforts provision (which Bristol-Myers concedes (at 2) it does not contest for purposes of its Motion), that the Trustee provided Bristol-Myers formal notice of this breach on March 4, 2021, and that Bristol-Myers did not cure this breach for over ninety days. Compl. ¶ 86.

Bristol-Myers wrongly contends that after the CVR Agreement terminated, the Trustee could never comply with the notice provision in Section 8.1(b), and an Event of Default under Section 8.1(b) could never occur, for two reasons: (1) "[t]here could be no 'continuance' of any alleged breach" of the Diligent Efforts provision for ninety days once the CVR Agreement terminated "because the Company did not have any further obligation to perform under that provision," Br. at 15, and (2) it was not "possible for an alleged failure to use Diligent Efforts to achieve the [L]iso-cel milestone to be 'remedied' given that the written notice was sent after the FDA already had approved [L]iso-cel and months after the [L]iso-cel milestone date already passed," Br. at 16.

Bristol-Myers cites no authority for its argument that a breach or default ceases to continue once the CVR Agreement terminates. That is little surprise: this Court recently rejected that precise argument in *New York Wheel Owner LLC v. Mammoet Holding B.V.*, 481 F. Supp. 3d 216, 236–37 (S.D.N.Y. 2020) (Furman, J.). In *New York Wheel*, the defendant entered a guaranty agreement with the plaintiff to guarantee the performance of a developer under a contract (the "DBA") that the developer had entered with the plaintiff. *Id.* at 236. The guaranty agreement stated that the plaintiff could "demand performance or payment" from the defendant "when 'a default by the

[developer] under the [DBA] has occurred and is continuing.'" *Id.* (second alteration in original). The defendant argued "that, to the extent the [developer] defaulted, its default was not 'continuing' because the [DBA] was terminated." *Id.*

"The Court disagree[d]." *Id.* at 237. As this Court explained, "[a] party is in default when it fails to perform its contractual obligations," and "[o]rdinarily, termination of an agreement does not change that state of affairs; the terminated party remains liable for the breach." *Id.* Thus, this Court concluded that the condition that the default be "continuing" "is more reasonably read to prohibit a demand based on a breach that the [developer] has cured." *Id.* In other words, "the requirement that the [developer's] default be 'continuing'" acts to "exclude any breach that is cured or excused by the party to which the [developer's] obligation is owed." *Id.* But it does not eliminate liability for pre-termination breaches. So too here.

Bristol-Myers conflates its obligation to use Diligent Efforts (which arguably ceases when the CVR Agreement terminates) with its past breaches of that obligation before the CVR Agreement terminated. Those breaches continue until they are remedied, as this Court held in *New York Wheel*. *Id.* And as in *New York Wheel*, the commonsense conclusion that a breach continues after termination is reinforced by other contractual language: the CVR Agreement expressly states that Bristol-Myers remains liable for such a breach, and that the Trustee's enforcement rights under Article 8 survive, after the CVR Agreement terminates. *See* Compl. Ex. A § 1.16 (stating that "termination … shall not relieve any Party of any liability" and that Article 8 "shall survive"); *N.Y. Wheel*, 481 F. Supp. 3d at 237 (noting that the interpretation of "continuing" is supported by the fact that "the Completion Guaranty contemplates the possibility that New York Wheel might terminate the DBA prior to its completion and expressly provides that the guarantors' obligations 'shall survive'").

The absurd results from Bristol-Myers's interpretation confirm that Bristol-Myers is wrong. Namely, Bristol-Myers's interpretation would create an exception to liability for the last ninety days of the CVR Agreement. If Bristol-Myers were correct, it could have ceased making any effort to get Liso-cel approved, petitioned for the FDA to delay approval until after December 31, 2020, or even wrongfully withdrawn the Liso-cel BLA, at any point after October 2, 2020 (ninety days before the Liso-cel Milestone), with impunity—because ninety days could not then pass between any notice of that breach and the termination of the CVR Agreement upon the failure of the Liso-cel Milestone on January 1, 2021. No one could, or did, intend such an absurd result. *See, e.g.*, *Lanmark Grp., Inc. v. N.Y.C. Sch. Const. Auth.*, 50 N.Y.S.3d 349, 351 (1st Dep't 2017) ("A 'contract should not be interpreted to produce a result that is absurd, commercially unreasonable or contrary to the reasonable expectations of the parties.'" (quoting *In re Lipper Holdings, LLC*, 766 N.Y.S.2d 561, 562 (1st Dep't 2003))).

The absurdity of Bristol-Myers's ninety-day-immunity interpretation is not hypothetical. The Trustee has alleged that several critical breaches of Bristol-Myers's Diligent Efforts obligation occurred within ninety days of the CVR Agreement's purported termination.[2] For example, the Trustee has alleged that Bristol-Myers breached its Diligent Efforts obligation by (1) "inadequately prepar[ing] the Juno Facility," in October 2020 resulting in "the FDA inspectors f[inding] numerous, substantial deviations from known or readily determinable FDA regulations and guidelines," Compl. ¶ 10; *see also id.* ¶¶ 65–66; (2) providing a response to the FDA's findings weeks later that contained "unclear and questionable points," *id.* ¶ 10; *see also id.* ¶ 67; (3) failing to adequately prepare the Lonza Facility in December 2020, resulting in a "litany of errors" identified

[2] As discussed in Section II, Bristol-Myers's breach of its obligation to provide the Trustee access to Bristol-Myers's books and records occurred just days before the CVR Agreement terminated.

by the FDA, some of which overlapped with those identified at the Juno Facility, *id.* ¶ 69–71; and (4) providing an inadequate response to the FDA's findings at the Lonza Facility, *id.* ¶ 72. But according to Bristol-Myers, the Trustee could never bring suit based on any of this misconduct. No reasonable commercial actor would contract for such an absurd result.

Bristol-Myers is also wrong (at 16) that it is not "possible for an alleged failure to use Diligent Efforts to achieve the [L]iso-cel milestone to be 'remedied' given that the written notice was sent after the FDA already had approved [L]iso-cel and months after the [L]iso-cel milestone date already had passed." To the contrary, Bristol-Myers could have provided (and still could provide) several remedies. Most obviously, Bristol-Myers could remedy its breaches, as centuries of jurisprudence dictate, through the payment of money. *See Suber v. VVP Servs., LLC*, No. 20 Civ. 8177, 2021 WL 2894810, at *3 (S.D.N.Y. July 9, 2021) ("[I]t is elemental that 'damages are always the default remedy for breach of contract.'" (quoting *United States v. Winstar Corp.*, 518 U.S. 839, 885 (1996))). Moreover, Bristol-Myers could have reinstated the CVR Agreement and waived or extended the Liso-cel Milestone or reached a compromise that resolved the breaches.[3] Because Bristol-Myers has provided no remedy, the breaches continued for ninety days after notice (and are still continuing).[4]

Finally, Bristol-Myers's litigation position is a backdoor attempt to grant itself a not-bargained-for release of liability. If Bristol-Myers is correct, then no one can hold Bristol-Myers

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[3] Even if future efforts to meet the Milestone were the only way to remedy the breach, Bristol-Myers was already under an ongoing obligation to exercise Diligent Efforts, but did not do so. Providing notice would have been "useless" and, therefore, excused. *See Giuffre Hyundai, Ltd. v. Hyundai Motor Am.*, 756 F.3d 204, 209–10 (2d Cir. 2014).

[4] Additionally, Section 8.1(b) does not condition an Event of Default on the ability to cure through performance; it requires only "the continuance of such default or breach" for ninety days after notice. *Id.* § 8.1(b); *see also N.Y. Wheel*, 481 F. Supp. 3d at 248 ("[C]ourts should not lightly conclude that a provision imposes a condition precedent.").

liable for the breaches alleged in the Complaint. The CVR Agreement requires any CVR holder to "give[] to the Trustee written notice of default and of the continuance thereof" before bringing suit individually. Compl. Ex. A § 8.6 (emphasis added). But no holder may give such a notice because, in Bristol-Myers's view, no default can continue after the CVR Agreement terminates. So, because neither the Trustee nor the holders purportedly can assert a continuing breach or default after the CVR Agreement terminates, neither can bring suit.[5]

Such a result is precluded by the CVR Agreement, which states that "the termination of this CVR Agreement shall not relieve any Party of any liability arising from any material breach of its obligations under this CVR Agreement occurring prior to the Termination Date." *Id.* § 1.16. It is also contrary to New York law, which provides that "[a] release will not be given effect unless it contains an 'explicit, unequivocal statement of a present promise to release [a party] from liability.'" *Golden Pac. Bancorp v. FDIC*, 273 F.3d 509, 515 (2d Cir. 2011) (quoting *Bank of Am. Nat'l Tr. & Sav. Ass'n v. Gillaizeau*, 766 F.2d 709, 713 (2d Cir. 1985)). The CVR Agreement contains no such express language. Had the parties wished to limit Bristol-Myers's liability to breaches that occurred and were noticed at least ninety days before the CVR Agreement terminated, then as made plain by cases Bristol-Myers cites,[6] they would have done so expressly. They did not.

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[5] Bristol-Myers's position is also inconsistent with Section 7.5, which requires Bristol-Myers to "keep … true, complete and accurate records in reasonably sufficient detail" for three years after the CVR Agreement's termination "to enable the Holders to determine if the Company has complied with its obligations." It makes no sense to require Bristol-Myers to retain documents for three years after termination if no one may notice a default and bring suit after termination.

[6] *See N.Y. Wheel*, 481 F. Supp. 3d at 246 (collecting cases in which contracts "'specifically provide[] that the failure to comply' with contractual notice requirements 'would constitute a waiver' of a … 'claim for damages'" (emphasis added) (quoting *Morelli Masons, Inc. v. Peter Scalamandre & Sons*, 294 A.D.2d 113 (1st Dep't 2002))); *Rojas v. Don King Prods., Inc.*, No. 11 Civ. 8468, 2012 WL 760336, at *1 (S.D.N.Y. Mar. 6, 2012) (construing a provision that expressly stated that "[i]n the event that [the plaintiff] fails for any reason whatsoever to provide notice to

Bristol-Myers fails to address any of this and instead relies on inapposite cases, none of which addresses a situation in which the plaintiff, as here, provided notice and waited for the requisite period after notice before bringing suit. Instead, Bristol-Myers relies on cases in which (1) the plaintiff failed to plead compliance with a notice provision, *U.S. Bank Nat'l Ass'n v. U.S. Timberlands Klamath Falls LLC*, C.A. No. 112-N, 2004 WL 1699057 at *3 n.26 (Del. Ch. July 29, 2004); *Prudential Ins. Co. of Am. v. Hilton Hotels Corp.*, No. 95 Civ. 5575, 1996 WL 340002, at *2 (S.D.N.Y. June 19, 1996); (2) the plaintiff never provided notice, *E. 18th Mgmt. Corp. v. CSC ServiceWorks, Inc.*, No. 18 Civ. 4068, 2019 WL 2994447, at *7 (E.D.N.Y. July 9, 2019); *USI Ins. Servs. LLC v. Miner*, 801 F. Supp. 2d 175, 182 (S.D.N.Y. 2011); *Point Prods. A.G. v. Sony Music Entm't Inc.*, No. 93 Civ. 4001, 2000 WL 1006236, at *4 (S.D.N.Y. July 20, 2000); *I.J. Litwak & Co. v. Gen. Signal Corp.*, 741 N.Y.S.2d 426, 427 (2d Dep't 2002) (per curiam); or (3) notice was not required because it was futile, *Vision Ent. Worldwide, LLC v. Mary Jane Prods., Inc.*, No. 13 Civ. 4215, 2014 WL 5369776, at *11 (S.D.N.Y. Oct. 17, 2014). These cases do not support Bristol-Myers's position. Bristol-Myers's Motion should be denied.[7]

B. New York Law Prevents Bristol-Myers From Relying On Its Own Breaches To Escape Liability

Bristol-Myers's Motion should be denied for another independent, sufficient reason. Under New York law, "a party may not insist upon performance of a condition precedent when its nonperformance has been caused by the party [it]self." *Royal Park Invs. SA/NV v. Deutsche Bank Nat'l Tr. Co.*, No. 14 Civ. 4394, 2016 WL 439020, at *5 (S.D.N.Y. Feb. 3, 2016) (alteration in

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[the defendant] of such claimed breach within the 30 Day Period, … [the plaintiff] shall be deemed to have waived and released and hereby does waive and release [the defendant] from any and all liability with respect to such claimed breach").

[7] At a minimum, the CVR Agreement does not unambiguously support Bristol-Myers's position. That, too, mandates denial of Bristol-Myer's Motion. *See Orlander v. Staples, Inc.*, 802 F.3d 289, 295 (2d Cir. 2015).

original) (quoting *Bank of N.Y. v. Tyco Int'l Grp., S.A.*, 545 F. Supp. 2d 312, 324 n.81 (S.D.N.Y. 2008)). Bristol-Myers's arguments violate this principle.

First, Bristol-Myers argues (at 12–13) that an Event of Default is a condition precedent to the Trustee bringing suit and that this condition has not been satisfied. The Complaint alleges that Bristol-Myers is responsible for the termination of the CVR Agreement which, according to Bristol-Myers, is what has prevented an Event of Default from occurring. Compl. ¶ 80. More specifically, Bristol-Myers's nonperformance of its Diligent Efforts obligation wrongfully caused the CVR Agreement's termination and resulted in the Trustee's purported inability to assert an Event of Default. *Id.* Thus, if Bristol-Myers is right that the CVR Agreement's termination caused the failure of a requisite condition for the Trustee to bring suit, Bristol-Myers cannot insist upon that condition. *See, e.g.*, *Royal Park*, 2016 WL 439020, at *5.

Second, Bristol-Myers was under an affirmative obligation to provide "the Trustee written notice of the occurrence of any Event of Default or other default under this CVR Agreement within five (5) Business Days of its becoming aware of such Event of Default or other default." Compl. Ex. A § 7.11. It failed to do so and, therefore, cannot use a purported lack of notice of its own breaches as a sword. *See Royal Park*, 2016 WL 439020, at *5 (holding the defendant could not "avoid liability by 'insist[ing] upon' written notice" when the defendant also had "an affirmative duty to notify" the other parties to the contract of any discovered breach but had not done so (quoting *Tyco*, 545 F. Supp.2d at 324 n.81)).

The Trustee has alleged that Bristol-Myers was aware it had breached its Diligent Efforts obligation. Bristol-Myers knew that it had omitted "fundamental components of [the Liso-cel] BLA," Compl. ¶ 52, resulting in the major amendment, an extremely rare result for a Breakthrough Therapy and Regenerative Medicine Advanced Therapy selected for Priority Review, *id.* ¶¶ 53, 55.

It also "knew that the Pre-License Inspections were critical to timely FDA approval of the Liso-cel BLA," *id.* ¶ 62, yet did not prepare either the Juno or Lonza Facilities adequately for their pre-license inspections, resulting in Bristol-Myers "acknowledg[ing] many of the failures" to comply with "basic FDA standards" at the Juno Facility, *id.* ¶ 67; *see id.* ¶¶ 66, 69–71, 73. The FDA told Bristol-Myers that its response to the Juno Form 483 contained "unclear and questionable points," *id.* ¶ 67, and Bristol-Myers had to supplement both responses to the Forms 483 issued for the Juno and Lonza Facilities, *id.* ¶¶ 67, 72. Bristol-Myers knew (and should have known) that these numerous issues resulted from its breaches of its Diligent Efforts obligation. Yet Bristol-Myers failed to provide the required notice to the Trustee. Bristol-Myers cannot insist on written notice from the Trustee when it failed to provide notice itself.

C. An Event Of Default Is Not Required For The Trustee To Bring Suit

Even if an Event of Default had not occurred, and Bristol-Myers were not precluded from seeking to enforce the notice requirement, the Trustee would still have the right to bring suit. Section 8.9(b) of the CVR Agreement expressly provides that "[n]othing in this CVR Agreement shall impair the right of the Trustee in its discretion to take any action deemed proper by the Trustee and which is not inconsistent with … direction or directions by Holders." Compl. Ex. A § 8.9(b). Because the Trustee has deemed that a lawsuit is proper, it may bring suit.

Bristol-Myers does not address Section 8.9(b). Instead, it cites (at 13–14) only Sections 8.1 and 8.4, pointing out that both provisions apply only when there is an Event of Default. But Sections 8.1 and 8.4 are not exclusive, *see* Compl. Ex. A § 8.8(a), and they perform a different function from Section 8.9(b). Section 8.1 mandates that the Trustee sue after an Event of Default. *Id.* § 8.1 (stating that the Trustee "shall" bring suit "[i]f an Event of Default … occurs and is continuing"). Section 8.4 clarifies that after an Event of Default—when the Trustee must bring suit—the Trustee has discretion to select the type of judicial proceeding and relief that it "deem[s]

most effectual." These provisions do not restrict the Trustee's ability under Section 8.9(b) to take "any action" the Trustee deems proper.

With the contractual language against it, Bristol-Myers resorts (at 14) to inapposite caselaw to assert that an Event of Default is always necessary for the Trustee to sue. Neither *Timberlands*, 2004 WL 1699057, nor *UMB Bank, N.A. v. Neiman Marcus Group, Inc.*, 128 N.Y.S.3d 823 (N.Y. Sup. Ct. 2020) involved an agreement that provided, as here, that the trustee has the "right … in its discretion to take any action deemed proper by the Trustee," Compl. Ex. A § 8.9(b), and so, of course, no such provision was raised or addressed in those cases, *cf.* Ex. 1 (*Timberlands* Indenture); Exs. 2–7 (*Neiman Marcus* Indentures and Supplemental Indentures). The CVR Agreement does, and that difference is dispositive.

II. Bristol-Myers's Breach Of Its Obligation To Provide Books And Records Is Adequately Pleaded

In seeking to dismiss the books and records claim, Bristol-Myers doubles down on its erroneous construction. It not only contends (at 19) that its failure to respond to the books and records request, made before the CVR Agreement terminated, could never become an Event of Default, but also argues (at 19–20) that it could run out the clock by not responding to the request before the CVR Agreement terminated. Bristol-Myers then states (at 20–21), without explanation, that the Trustee's damages "are not legally cognizable." Bristol-Myers's arguments are baseless.

First, as addressed in Section I, Bristol-Myers is wrong that the CVR Agreement's termination stops a breach from continuing and renders the breach not an Event of Default. Bristol-Myers's argument on the books and records claim only highlights the absurdity of its position. Bristol-Myers breached in the last few days before the CVR Agreement terminated. Compl. ¶¶ 15, 75–77. If a breach ceases to continue once the breached obligation terminates, then the Trustee

could never seek a remedy for Bristol-Myers's breach of its books and records obligation. The Court should reject Bristol-Myers's invitation to create a ninety-day exception to liability.

Second, contrary to Bristol-Myers's claim (at 19) that making a "request to examine records just two days before the CVR Agreement automatically terminated is … fatal," the CVR Agreement nowhere creates a deadline for the Trustee to request books and records more than two days before the CVR Agreement terminates. Rather, it "entitle[s]" the Trustee "to examine the pertinent books and records of the Company … in a manner so as to not unreasonably interfere with the normal business operations of the Company or any of its Affiliates." Compl. Ex. A § 4.2(f).

Bristol-Myers baldly asserts (at 20) that during the winter holidays, "most corporations would not be well-positioned to respond immediately to unexpected information requests" and that complying with the Trustee's request "undoubtedly would have 'unreasonably interfere[d]' with important 'business operations,' including those that might have been associated with the pending [Liso-cel] application." Bristol-Myers also asserts (at 20) that the CVR Agreement allows outside counsel to review books and records before production—although Bristol-Myers does not state whether outside counsel would have needed to review these books and records or would not have had time to do so. These are, at most, factual issues not suited for resolution on a motion to dismiss. *Kelly-Brown v. Winfrey*, 717 F.3d 295, 313 (2d Cir. 2013) (noting that a court's "role in considering a motion to dismiss is not to resolve these sorts of factual disputes"). But even more fundamentally, Bristol-Myers is not like "most corporations." Instead, it had an ongoing affirmative obligation to "use commercially reasonable efforts to keep, and [to] cause its Subsidiaries to use commercially reasonable efforts to keep, true, complete and accurate records in reasonably sufficient detail to enable the Holders to determine if the Company has complied with its obligations

under the CVR Agreement." Compl. Ex. A § 7.5. In other words, Bristol-Myers was contractually obligated to have the books and records ready for review.

Finally, Bristol-Myers's assertion (at 20–21) that the books and records claim should be dismissed because damages for the claim "are not legally cognizable" is meritless. As an initial matter, "nominal damages are always available in a breach of contract action even if a party cannot prove general or consequential damages." *Compania Embotelladora Del Pacifico, S.A. v. Pepsi Cola Co.*, 976 F.3d 239, 247 n.10 (2d Cir. 2020) (collecting cases).[8] But even setting that aside, Bristol-Myers is wrong that the Trustee's alleged damages are not cognizable because the Trustee has not plausibly alleged that its damages were "directly" and "proximately" caused by Bristol-Myers's breach. The Trustee expressly alleged that it "has incurred expenses to engage in an investigation that would have been obviated or reduced in scope had Bristol-Myers complied with its obligations." Compl. ¶ 104. In any event, "[a]t the motion to dismiss stage, the party pleading a claim need not specify the measure of damages nor plead specific proof of causation." *Bos. Consulting Grp., Inc. v. NCR Corp.*, No. 19 Civ. 10156, 2020 WL 5731963, at *6 (S.D.N.Y. Sept. 24, 2020).

CONCLUSION

For the reasons stated above, the Trustee respectfully request that the Court deny Bristol-Myers's Motion.

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[8] Yet again, the cases Bristol-Myers cites are inapposite. They are post-trial decisions concerning whether the plaintiff proved that the breach of contract caused the specific damages requested—not whether a complaint plausibly alleged a viable breach of contract claim. *See Nat'l Mkt. Share, Inc. v. Sterling Nat'l Bank*, 392 F.3d 520, 525, 530 (2d Cir. 2004) (post-trial appeal by prevailing party concerning whether prevailing party should have received more than nominal damages for successful breach of contract claim); *Kenford Co. v. Erie County*, 67 N.Y.2d 257, 260–61 (1986) (post-trial decision addressing proof required for "loss of future profits"—not an issue here—after liability established).

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Respectfully submitted,

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